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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/493,803 01/28/00 GOOD

000959
LAHIVE & COCKFIELD
28 STATE STREET
BOSTON MA 02109

HM12/1022

EXAMINER

A	AGZ-002
ART UNIT	PAPER NUMBER

DATE MAILED, D

1638

10/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/493,803	Applicant(s) GOOD, ALLEN G.	
	Examiner David H Kruse	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8,26,37-39 and 64-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,8,26,37-39 and 64-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. This Office Action is in response to the Amendment and Response filed 7 August 2001 as Paper No. 9.
2. The objections to the Title and Abstract are withdrawn in view of Applicant's amendments.
3. The rejection of claims 8, 26, 38 and 38 under 35 U.S.C. § 112, second paragraph, as indefinite is withdrawn in view of Applicant's amendment to the claims.
4. The rejection of Claims 7, 8, 26 and 37-39 under 35 U.S.C. § 102(b) as being anticipated by Dixon *et al* (U.S. Patent 5,750,399) is withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

6. Claims 7, 8, 26, and 37-39 remain rejected and Claims 64 -68 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method for directing root-specific expression of a target gene in a plant with the btg-26 promoter of SEQ ID NO: 1 wherein said promoter is osmotically regulated and a seed comprising said promoter, does not reasonably provide enablement for a method for directing root-specific expression of a target gene in a plant with any root-specific promoter and wherein said root-specific promoter is environmentally or developmentally regulated. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of

record as set forth in the last Office action mailed 12 February 2001. Applicant's arguments filed 7 August 2001 have been fully considered but they are not persuasive.

Applicant argues that the specification teaches the isolation of the osmotic stress-induced promoter *btg-26* and a method of root-specific expression using said promoter. In addition, Applicant argues that root-specific promoters and stress-induced promoters were well known in the art at the time of filing (pages 6 and 7 of the Remarks). The Examiner responds, the instant claims are directed to a method and plants comprising a stress-induced genetic regulatory element, which directs root-specific expression of a gene operably linked to said regulatory element. Such a regulatory element, in view of the prior art (i.e. Montgomery 1993), would comprise multiple elements within the coding region each having distinct function. Without extensive guidance as to which elements are involved in either stress-induced transcription promotion or root-specific transcription promotion, it would have required undue experimentation by one of skill in the art to identify the genus of regulatory elements that are both stress-induced and root-specific, or construct such regulatory elements, as broadly claimed.

Claim Rejections - 35 USC § 102

7. Claims 7, 9, 26 and 37-39 remain rejected and Claims 64-68 are rejected under 35 U.S.C. §102(e) as being anticipated by Good *et al* (U.S. Patent 6,084,153). This rejection is repeated for the reason of record as set forth in the last Office action mailed 12 February 2001. Applicant's arguments filed 7 August 2001 have been fully considered but they are not persuasive.

Applicant argues that Good does not teach or suggest a method for directing root-specific expression of a target gene or a seed, which directs root-specific expression of a target gene (page 9 of the Remarks). The Examiner reiterates that Good discloses Applicant's SEQ ID NO: 1 encoding the *btg-26* promoter, in addition to constructs and plants transformed therewith, and a method of producing a plant comprising said promoter. The *btg-26* promoter disclosed by both Good and Applicant inherently possesses the characteristics of stress-induction and root-specific functionality. Hence, Good has previously disclosed Applicant's claimed method (claims 7, 8 and 26) and seed, transformed plant cell and plant (claims 37-39 and 64-68).

Double Patenting

8. Claims 7, 8, 26 and 37-39 remain and Claims 64-68 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,084,153. This rejection is repeated for the reason of record as set forth in the last Office action mailed 12 February 2001. Applicant states that a terminal disclaimer will be filed upon an indication from the Examiner that the application is otherwise in condition for allowance (page 10 of the Remarks).

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Conclusion

9. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

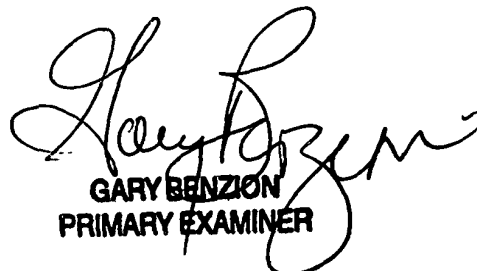
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3482.

David H. Kruse, Ph.D.
22 October 2001


GARY BENZION
PRIMARY EXAMINER